

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO**

WILLIAM SETZER and

PAMELA SETZER

Plaintiffs,

v.

MONSANTO COMPANY

Defendant.

Case No.: _____

Judge: _____

COMPLAINT

WITH JURY DEMAND ENDORSED HEREON

Plaintiffs William Setzer and Pamela Setzer, by and through their undersigned counsel, for their Complaint against Defendant Monsanto Company, aver and state:

Introduction

1. In 1970, Defendant Monsanto Company, Inc. (“Monsanto”) discovered the herbicidal properties of glyphosate and began marketing it in products in 1974 under the brand name Roundup[®]. Roundup[®] is a non-selective herbicide used to kill weeds that commonly compete with the growing of crops. In addition to the active ingredient glyphosate, Roundup[®] contains the surfactant Polyethoxylated tallow amine (POEA) and/or adjuvants and other so-called “inert” ingredients. In 2001, glyphosate was the most-used pesticide active ingredient in American agriculture with 85–90 million pounds used annually. That number grew to 185 million pounds in 2007.¹ As of 2013, glyphosate was the world’s most widely used herbicide.

2. Monsanto is a multinational agricultural biotechnology corporation based in St. Louis, Missouri, and incorporated in Delaware. It is the world's leading producer of glyphosate. As of

¹ Arthur Grube et al., U.S. Env'tl. Prot. Agency, *Pesticides Industry Sales and Usage, 2006–2007 Market Estimates* 14 (2011), available at http://www.epa.gov/pesticides/pestsales/07pestsales/market_estimates2007.pdf.

2009, Monsanto was the world's leading producer of seeds, accounting for 27% of the world seed market.² The majority of these seeds are of the Roundup Ready[®] brand. The stated advantage of Roundup Ready[®] crops is that they substantially improve a farmer's ability to control weeds, because glyphosate can be sprayed in the fields during the growing season without harming the crops. In 2010, an estimated 70% of corn and cotton and 90% of soybean fields in the United States were Roundup Ready[®].³

3. Monsanto's glyphosate products are registered in 130 countries and approved for use on over 100 different crops.⁴ They are ubiquitous in the environment. Numerous studies confirm that glyphosate is found in rivers, streams, and groundwater in agricultural areas where Roundup[®] is used.⁵ It has been found in food,⁶ in the urine of agricultural workers,⁷ and even in the urine of urban dwellers who are not in direct contact with glyphosate.⁸

4. On March 20, 2015, the International Agency for Research on Cancer ("IARC"), an agency of the World Health Organization ("WHO"), issued an evaluation of several herbicides, including glyphosate. That evaluation was based, in part, on studies of exposures to glyphosate

² ETC Group, *Who Will Control the Green Economy?* 22 (2011), available at http://www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf.

³ William Neuman & Andrew Pollack, *Farmers Cope With Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, available at <http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewanted=all>.

⁴ Monsanto, *Backgrounder-History of Monsanto's Glyphosate Herbicides* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf.

⁵ See U.S. Geological Survey, *USGS Technical Announcement: Widely Used Herbicide Commonly Found in Rain and Streams in the Mississippi River Basin* (2011), available at <http://www.usgs.gov/newsroom/article.asp?ID=2909>; see also U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate*, available at <http://www.epa.gov/safewater/pdfs/factsheets/soc/tech/glyphosa.pdf>.

⁶ Thomas Bohn et al., *Compositional Differences in Soybeans on the Market: Glyphosate Accumulates in Roundup Ready GM Soybeans*, 153 FOOD CHEMISTRY 207 (2013), available at <http://www.sciencedirect.com/science/article/pii/S0308814613019201>.

⁷ John F. Acquavella et al., *Glyphosate Biomonitoring for Farmers and Their Families: Results from the Farm Family Exposure Study*, 112(3) ENVTL. HEALTH PERSPECTIVES 321 (2004), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241861/>; Kathryn Z. Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, 112 IARC Monographs 76, section 5.4 (2015), available at [http://dx.doi.org/10.1016/S1470-2045\(15\)70134-8](http://dx.doi.org/10.1016/S1470-2045(15)70134-8).

⁸ Dirk Brändli & Sandra Reinacher, *Herbicides found in Human Urine*, 1 ITHAKA JOURNAL 270 (2012), available at <http://www.ithaka-journal.net/druckversionen/e052012-herbicides-urine.pdf>.

in several countries around the world, and it traces the health implications from exposure to glyphosate since 2001.

5. On July 29, 2015, IARC issued the formal monograph relating to glyphosate. In that monograph, the IARC Working Group provides a thorough review of the numerous studies and data relating to glyphosate exposure in humans.

6. The IARC Working Group classified glyphosate as a Group 2A herbicide, which means that it is *probably carcinogenic to humans*. The IARC Working Group concluded that the cancers most associated with glyphosate exposure are non-Hodgkin lymphoma and other haematopoietic cancers, including lymphocytic lymphoma / chronic lymphocytic leukemia, B-cell lymphoma, and multiple myeloma.⁹

7. The IARC evaluation is significant. It confirms what has been believed for years: that glyphosate is toxic to humans.

8. Nevertheless, Monsanto, since it began selling Roundup[®], has represented it as safe to humans and the environment. Indeed, Monsanto has repeatedly proclaimed and continues to proclaim to the world, and particularly to United States consumers, that glyphosate-based herbicides, including Roundup[®], create no unreasonable risks to human health or to the environment.

Jurisdiction and Venue

9. Federal diversity jurisdiction in this Court is proper under 28 U.S.C. § 1332 because Plaintiffs are citizens of Ohio, a different state than the Defendant's states of citizenship (Missouri and Delaware), and the aggregate amount in controversy exceeds \$75,000, exclusive of interest and costs.

10. This Court has personal jurisdiction over Monsanto under 735 Ill. Comp. Stat. 5/2-209(a)(1) and (b)(4) because Monsanto transacts business in Ohio and is a corporation doing

⁹ See Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, *supra*.

business within Ohio. Monsanto knows or should have known that its Roundup[®] products are and were sold throughout the Ohio, and, more specifically, caused Roundup[®] to be sold to Plaintiffs and/or to their employers in Ohio.

11. In addition, Monsanto maintains sufficient contacts with the State of Ohio such that this Court's exercise of personal jurisdiction over it does not offend traditional notions of fair play and substantial justice.

12. Venue is proper within this District under 28 U.S.C. § 1391(b)(2) because the events giving rise to this action happened in or are closely related to this District.

Parties

Plaintiff William Setzer

13. Plaintiff William Setzer is a natural person, is a citizen of the State of Ohio, and is a resident of Lake County, Ohio.

14. Mr. Setzer was exposed to Roundup[®] in or around Painesville, Ohio, from around 1991 through 2016. He was diagnosed with Non-Hodgkin lymphoma in August 2016.

15. Plaintiff Pamela Setzer is a natural person, is a citizen of the State of Ohio, is a resident of Lake County, Ohio, and is the spouse of Plaintiff William Setzer.

Defendant Monsanto Company

16. Defendant Monsanto Company is a corporation created under the laws of the State of Delaware with its headquarters and principal place of business in St. Louis, Missouri.

Facts

17. At all times relevant to this complaint, Monsanto was the entity that discovered the herbicidal properties of glyphosate and the manufacturer of Roundup[®], which contains the active ingredient glyphosate and the surfactant POEA, as well as adjuvants and other "inert"

ingredients. Glyphosate is a broad-spectrum, non-selective herbicide used in a wide variety of herbicidal products around the world.

18. Plants treated with glyphosate translocate the systemic herbicide to their roots, shoot regions, and fruit, where it interferes with the plant's ability to form aromatic amino acids necessary for protein synthesis. Treated plants generally die within two to three days. Because plants absorb glyphosate, it cannot be completely removed by washing or peeling produce or by milling, baking, or brewing grains.

19. For nearly 40 years, farms across the world have used Roundup[®] without knowing of the dangers its use poses. That is because when Monsanto first introduced Roundup[®], it touted glyphosate as a technological breakthrough: it could kill almost every weed without causing harm either to people or to the environment. Of course, history has shown that not to be true. According to the WHO, the main chemical ingredient of Roundup[®]—glyphosate—is a probable cause of cancer. Those most at risk are farm workers and other individuals with workplace exposure to Roundup[®], such as garden center workers, nursery workers, and landscapers. Agricultural workers are, once again, victims of corporate greed. Monsanto assured the public that Roundup[®] was harmless. In order to prove this, Monsanto has championed falsified data and has attacked legitimate studies that revealed Roundup[®]'s dangers. Monsanto has led a prolonged campaign of misinformation to convince government agencies, farmers and the general population that Roundup[®] is safe.

The Discovery of Glyphosate and Development of Roundup[®]

20. The herbicidal properties of glyphosate were discovered in 1970 by Monsanto chemist John Franz. The first glyphosate-based herbicide was introduced to the market in the mid-1970s under the brand name Roundup[®].¹⁰ From the outset, Monsanto marketed Roundup[®] as a “safe”

¹⁰ Monsanto, *Backgrounder, History of Monsanto's Glyphosate Herbicide* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/back_history.pdf.

general-purpose herbicide for widespread commercial and consumer use. It still markets Roundup[®] as safe today.¹¹

21. In addition to the active ingredient glyphosate, Roundup[®] formulations also contain adjuvants and other chemicals, such as the surfactant POEA, which are considered “inert” and therefore protected as “trade secrets” in manufacturing. Growing evidence suggests that these adjuvants and additional components of Roundup[®] formulations are not, in fact, inert and are toxic in their own right.

Registration of Herbicides under Federal Law

22. The manufacture, formulation, and distribution of herbicides, such as Roundup[®], are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA” or “Act”), 7 U.S.C. § 136 *et seq.* FIFRA requires that all pesticides be registered with the Environmental Protection Agency (“EPA” or “Agency”) prior to their distribution, sale, or use, except as described by the Act. 7 U.S.C. § 136a(a).

23. Because pesticides are toxic to plants, animals, and humans, at least to some degree, the EPA requires as part of the registration process, among other things, a variety of tests to evaluate the potential for exposure to pesticides, toxicity to people and other potential non-target organisms, and other adverse effects on the environment. Registration by the EPA, however, is not an assurance or finding of safety. The determination the Agency must make in registering or re-registering a product is not that the product is “safe,” but rather that use of the product in accordance with its label directions “will not generally cause unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(D).

24. FIFRA defines “unreasonable adverse effects on the environment” to mean “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” 7 U.S.C. § 136(bb). FIFRA thus

¹¹ Monsanto, *What is Glyphosate?* (Sep. 2, 2015), <http://www.monsanto.com/sitecollectiondocuments/glyphosate-safety-health.pdf>.

requires EPA to make a risk/benefit analysis in determining whether a registration should be granted or a pesticide allowed to continue to be sold in commerce.

25. The EPA and the State of California registered Roundup[®] for distribution, sale, and manufacture in the United States and the State of California.

26. FIFRA generally requires that the registrant, Monsanto in the case of Roundup[®], conducts the health and safety testing of pesticide products. The EPA has protocols governing the conduct of tests required for registration and the laboratory practices that must be followed in conducting these tests. The data produced by the registrant must be submitted to the EPA for review and evaluation. The government is not required, nor is it able, however, to perform the product tests that are required of the manufacturer.

27. The evaluation of each pesticide product distributed, sold, or manufactured is completed at the time the product is initially registered. The data necessary for registration of a pesticide has changed over time. The EPA is now in the process of re-evaluating all pesticide products through a Congressionally-mandated process called “re-registration.” 7 U.S.C. § 136a-1. In order to reevaluate these pesticides, the EPA is demanding the completion of additional tests and the submission of data for the EPA’s recent review and evaluation.

28. In the case of glyphosate, and therefore Roundup[®], the EPA had planned on releasing its preliminary risk assessment—in relation to the reregistration process—no later than July 2015. The EPA completed its review of glyphosate in early 2015, but it delayed releasing the risk assessment pending further review in light of the WHO’s health-related findings.

Scientific Fraud Underlying the Marketing and Sale of Glyphosate/Roundup[®]

29. Based on early studies showing that glyphosate could cause cancer in laboratory animals, the EPA originally classified glyphosate as *possibly carcinogenic to humans* (Group C) in 1985. After pressure from Monsanto, including contrary studies it provided to the EPA, the EPA changed its classification to *evidence of non-carcinogenicity in humans* (Group E) in 1991. In so

classifying glyphosate, however, the EPA made clear that the designation did not mean the chemical does not cause cancer: “It should be emphasized, however, that designation of an agent in Group E is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.”¹²

30. On two occasions, the EPA found that the laboratories hired by Monsanto to test the toxicity of its Roundup[®] products for registration purposes committed fraud.

31. In the first instance, Monsanto, in seeking initial registration of Roundup[®] by the EPA, hired Industrial Bio-Test Laboratories (“IBT”) to perform and evaluate pesticide toxicology studies relating to Roundup[®].¹³ IBT performed about 30 tests on glyphosate and glyphosate-containing products, including nine of the 15 residue studies needed to register Roundup[®].

32. In 1976, the United States Food and Drug Administration (“FDA”) performed an inspection of IBT that revealed discrepancies between the raw data and the final report relating to the toxicological impacts of glyphosate. The EPA subsequently audited IBT; it too found the toxicology studies conducted for the Roundup[®] herbicide to be invalid.¹⁴ An EPA reviewer stated, after finding “routine falsification of data” at IBT, that it was “hard to believe the scientific integrity of the studies when they said they took specimens of the uterus from male rabbits.”¹⁵

33. Three top executives of IBT were convicted of fraud in 1983.

¹² U.S. Env'tl. Prot. Agency, *Memorandum, Subject: SECOND Peer Review of Glyphosate 1* (1991), available at http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-103601_30-Oct-91_265.pdf.

¹³ Monsanto, *Backgrounder, Testing Fraud: IBT and Craven Laboratories* (Sep. 2, 2015), http://www.monsanto.com/products/documents/glyphosate-background-materials/ibt_craven_bkg.pdf.

¹⁴ U.S. Env'tl. Prot. Agency, *Summary of the IBT Review Program Office of Pesticide Programs* (1983), available at <https://nepis.epa.gov/Exe/ZyPDF.cgi/91014ULV.PDF?Dockey=91014ULV.PDF>.

¹⁵ Marie-Monique Robin, *The World According to Monsanto: Pollution, Corruption and the Control of the World's Food Supply* (2011) (citing U.S. Env'tl. Prot. Agency, *Data Validation, Memo from K. Locke, Toxicology Branch, to R. Taylor, Registration Branch*, Washington, D.C. (August 9, 1978)).

34. In the second incident of data falsification, Monsanto hired Craven Laboratories in 1991 to perform pesticide and herbicide studies, including for Roundup[®]. In that same year, the owner of Craven Laboratories and three of its employees were indicted, and later convicted, of fraudulent laboratory practices in the testing of pesticides and herbicides.¹⁶

35. Despite the falsity of the tests that underlie its registration, within a few years of its launch, Monsanto was marketing Roundup[®] in 115 countries.

The Importance of Roundup[®] to Monsanto's Market Dominance Profits

36. The success of Roundup[®] was key to Monsanto's continued reputation and dominance in the marketplace. Largely due to the success of Roundup[®] sales, Monsanto's agriculture division was out-performing its chemicals division's operating income, and that gap increased yearly. But with its patent for glyphosate expiring in the United States in the year 2000, Monsanto needed a strategy to maintain its Roundup[®] market dominance and to ward off impending competition.

37. In response, Monsanto began the development and sale of genetically engineered Roundup Ready[®] seeds in 1996. Since Roundup Ready[®] crops are resistant to glyphosate, farmers can spray Roundup[®] onto their fields during the growing season without harming the crop. This allowed Monsanto to expand its market for Roundup[®] even further; by 2000, Monsanto's biotechnology seeds were planted on more than 80 million acres worldwide and nearly 70% of American soybeans were planted from Roundup Ready[®] seeds. It also secured Monsanto's dominant share of the glyphosate/Roundup[®] market through a marketing strategy that coupled proprietary Roundup Ready[®] seeds with continued sales of its Roundup[®] herbicide.

38. Through a three-pronged strategy of increasing production, decreasing prices, and by coupling with Roundup Ready[®] seeds, Roundup[®] became Monsanto's most profitable product. In 2000, Roundup[®] accounted for almost \$2.8 billion in sales, outselling other herbicides by a

¹⁶ Monsanto, *Backgrounder, Testing Fraud: IBT and Craven Laboratories*, *supra*.

margin of five to one, and accounting for close to half of Monsanto's revenue.¹⁷ Today, glyphosate remains one of the world's largest herbicides by sales volume.

Monsanto has known for decades that it falsely advertises the safety of Roundup®

39. In 1996, the New York Attorney General ("NYAG") filed a lawsuit against Monsanto based on its false and misleading advertising of Roundup® products. Specifically, the lawsuit challenged Monsanto's general representations that its spray-on glyphosate-based herbicides, including Roundup®, were "**safer than table salt**" and "**practically non-toxic**" to mammals, birds, and fish. Among the representations the NYAG found deceptive and misleading about the human and environmental safety of glyphosate and/or Roundup® are the following:

- a) "Remember that environmentally friendly Roundup herbicide is biodegradable. It won't build up in the soil so you can use Roundup with confidence along customers' driveways, sidewalks and fences ..."
- b) "And remember that Roundup is biodegradable and won't build up in the soil. That will give you the environmental confidence you need to use Roundup everywhere you've got a weed, brush, edging or trimming problem."
- c) "Roundup biodegrades into naturally occurring elements."
- d) "Remember that versatile Roundup herbicide stays where you put it. That means there's no washing or leaching to harm customers' shrubs or other desirable vegetation."
- e) "This non-residual herbicide will not wash or leach in the soil. It ... stays where you apply it."

¹⁷ David Barboza, *The Power of Roundup; A Weed Killer Is A Block for Monsanto to Build On*, N.Y. TIMES, Aug. 2, 2001, available at <http://www.nytimes.com/2001/08/02/business/the-power-of-roundup-a-weed-killer-is-a-block-for-monsanto-to-build-on.html>.

- f) “You can apply Accord with ‘confidence because it will stay where you put it’ it bonds tightly to soil particles, preventing leaching. Then, soon after application, soil microorganisms biodegrade Accord into natural products.”
- g) “Glyphosate is less toxic to rats than table salt following acute oral ingestion.”
- h) “Glyphosate’s safety margin is much greater than required. It has over a 1,000-fold safety margin in food and over a 700-fold safety margin for workers who manufacture it or use it.”
- i) “You can feel good about using herbicides by Monsanto. They carry a toxicity category rating of ‘practically non-toxic’ as it pertains to mammals, birds and fish.”
- j) “Roundup can be used where kids and pets will play and breaks down into natural material.” This ad depicts a person with his head in the ground and a pet dog standing in an area which has been treated with Roundup.¹⁸

40. On November 19, 1996, Monsanto entered into an Assurance of Discontinuance with NYAG, in which Monsanto agreed, among other things, “to cease and desist from publishing or broadcasting any advertisements [in New York] that represent, directly or by implication” that:

- a) its glyphosate-containing pesticide products or any component thereof are safe, non-toxic, harmless or free from risk.

* * *

- b) its glyphosate-containing pesticide products or any component thereof manufactured, formulated, distributed or sold by Monsanto are biodegradable

* * *

- c) its glyphosate-containing pesticide products or any component thereof stay where they are applied under all circumstances and will not move through the environment by any means.

¹⁸ Attorney General of the State of New York, In the Matter of Monsanto Company, Assurance of Discontinuance Pursuant to Executive Law § 63(15) (Nov. 1996).

* * *

- d) its glyphosate-containing pesticide products or any component thereof are “good” for the environment or are “known for their environmental characteristics.”

* * *

- e) glyphosate-containing pesticide products or any component thereof are safer or less toxic than common consumer products other than herbicides;
- f) its glyphosate-containing products or any component thereof might be classified as “practically non-toxic.”

41. Monsanto did not alter its advertising in the same manner in any state other than New York, and on information and belief it still has not done so today.

42. In 2009, France’s highest court ruled that Monsanto had not told the truth about the safety of Roundup[®]. The French court affirmed an earlier judgement that Monsanto had falsely advertised its herbicide Roundup[®] as “biodegradable” and that it “left the soil clean.”¹⁹

Classifications and Assessments of Glyphosate

43. The IARC process for the classification of glyphosate followed IARC’s stringent procedures for the evaluation of a chemical agent. Over time, the IARC Monograph program has reviewed 980 agents. Of those reviewed, it has determined 116 agents to be Group 1 (Known Human Carcinogens); 73 agents to be Group 2A (Probable Human Carcinogens); 287 agents to be Group 2B (Possible Human Carcinogens); 503 agents to be Group 3 (Not Classified); and one agent to be Probably Not Carcinogenic.

44. The established procedure for IARC Monograph evaluations is described in the IARC Programme’s Preamble.²⁰ Evaluations are performed by panels of international experts, selected on the basis of their expertise and the absence of actual or apparent conflicts of interest.

¹⁹ *Monsanto Guilty in ‘False Ad’ Row*, BBC, Oct. 15, 2009, available at <http://news.bbc.co.uk/2/hi/europe/8308903.stm>.

45. One year before the Monograph meeting, the meeting is announced and there is a call both for data and for experts. Eight months before the Monograph meeting, the Working Group membership is selected and the sections of the Monograph are developed by the Working Group members. One month prior to the Monograph meeting, the call for data is closed and the various draft sections are distributed among Working Group members for review and comment. Finally, at the Monograph meeting, the Working Group finalizes review of all literature, evaluates the evidence in each category, and completes the overall evaluation. Within two weeks after the Monograph meeting, the summary of the Working Group findings are published in *The Lancet Oncology*, and within a year after the meeting, the finalized Monograph is published.

46. In assessing an agent, the IARC Working Group reviews the following information: (a) human, experimental, and mechanistic data; (b) all pertinent epidemiological studies and cancer bioassays; and (c) representative mechanistic data. The studies must be publicly available and have sufficient detail for meaningful review, and reviewers cannot be associated with the underlying study.

47. In March 2015, IARC reassessed glyphosate. The summary published in *The Lancet Oncology* reported that glyphosate is a Group 2A agent and probably carcinogenic in humans.

48. On July 29, 2015, IARC issued its Monograph for glyphosate, Monograph Volume 112. For Volume 112, a Working Group of 17 experts from 11 countries met at IARC from March 3–10, 2015 to assess the carcinogenicity of certain herbicides, including glyphosate. The March meeting culminated a nearly one-year review and preparation by the IARC Secretariat and the Working Group, including a comprehensive review of the latest available scientific evidence. According to published procedures, the Working Group considered “reports that have been published or accepted for publication in the openly available scientific literature” as well as “data from governmental reports that are publicly available.”

²⁰ World Health Org., *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble* (2006), available at <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

49. The studies considered the following exposure groups: (1) occupational exposure of farmers and tree nursery workers in the United States, forestry workers in Canada and Finland and municipal weed-control workers in the United Kingdom; and (2) para- occupational exposure in farming families.

50. Glyphosate was identified as the second-most used household herbicide in the United States for weed control between 2001 and 2007 and the most heavily used herbicide in the world in 2012.

51. Exposure pathways are identified as air (especially during spraying), water, and food. Community exposure to glyphosate is widespread and found in soil, air, surface water, and groundwater, as well as in food.

52. The assessment of the IARC Working Group identified several case control studies of occupational exposure in the United States, Canada, and Sweden. These studies show a human health concern from agricultural and other work-related exposure to glyphosate.

53. The IARC Working Group found an increased risk between exposure to glyphosate and NHL and several subtypes of NHL, and the increased risk persisted after adjustment for other pesticides.

54. The IARC Working Group also found that glyphosate caused DNA and chromosomal damage in human cells. One study in community residents reported increases in blood markers of chromosomal damage (micronuclei) after glyphosate formulations were sprayed.

55. In male CD-1 mice, glyphosate induced a positive trend in the incidence of a rare tumor: renal tubule carcinoma. A second study reported a positive trend for haemangiosarcoma in male mice. Glyphosate increased pancreatic islet-cell adenoma in male rats in two studies. A glyphosate formulation promoted skin tumors in an initiation-promotion study in mice.

56. The IARC Working Group also noted that glyphosate has been detected in the urine of agricultural workers, indicating absorption. Soil microbes degrade glyphosate to

aminomethylphosphoric acid (AMPA). Blood AMPA detection after exposure suggests intestinal microbial metabolism in humans.

57. The IARC Working Group further found that glyphosate and glyphosate formulations induced DNA and chromosomal damage in mammals, and in human and animal cells in utero.

58. The IARC Working Group also noted genotoxic, hormonal, and enzymatic effects in mammals exposed to glyphosate.²¹ Essentially, glyphosate inhibits the biosynthesis of aromatic amino acids, which leads to several metabolic disturbances, including the inhibition of protein and secondary product biosynthesis and general metabolic disruption.

59. The IARC Working Group also reviewed an Agricultural Health Study, consisting of a prospective cohort of 57,311 licensed pesticide applicators in Iowa and North Carolina.²² While this study differed from others in that it was based on a self-administered questionnaire, the results support an association between glyphosate exposure and multiple myeloma, hairy cell leukemia (HCL), and chronic lymphocytic leukemia (CLL), in addition to several other cancers.

Other Earlier Findings About Glyphosate's Dangers to Human Health

60. The EPA has a technical fact sheet, as part of its Drinking Water and Health, National Primary Drinking Water Regulations publication, relating to glyphosate. This technical fact sheet predates IARC's March 20, 2015 evaluation. The fact sheet describes the release patterns for glyphosate as follows:

Release Patterns

Glyphosate is released to the environment in its use as a herbicide for controlling woody and herbaceous weeds on forestry, right-of-way, cropped and non-cropped sites. These sites may be around water and in wetlands.

It may also be released to the environment during its manufacture, formulation, transport, storage, disposal and cleanup, and from spills. Since glyphosate is

²¹ Guyton et al., *Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon & Glyphosate*, *supra* at 77.

²² Anneclare J. De Roos et al., *Cancer Incidence Among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study*, 113 *Env'tl Health Perspectives* 49–54 (2005), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1253709/pdf/ehp0113-000049.pdf>.

not a listed chemical in the Toxics Release Inventory, data on releases during its manufacture and handling are not available.

Occupational workers and home gardeners may be exposed to glyphosate by inhalation and dermal contact during spraying, mixing, and cleanup. They may also be exposed by touching soil and plants to which glyphosate was applied. Occupational exposure may also occur during glyphosate's manufacture, transport storage, and disposal.²³

61. In 1995, the Northwest Coalition for Alternatives to Pesticides reported that in California, the state with the most comprehensive program for reporting of pesticide-caused illness, glyphosate was the third most commonly-reported cause of pesticide illness among agricultural workers.²⁴

The Toxicity of Other Ingredients in Roundup®

62. In addition to the toxicity of the active ingredient, glyphosate, several studies support the hypothesis that the glyphosate-based formulation in Defendant's Roundup® products is more dangerous and toxic than glyphosate alone. Indeed, as early as 1991, available evidence demonstrated that glyphosate formulations were significantly more toxic than glyphosate alone.²⁵

63. In 2002, a study by Julie Marc, entitled "Pesticide Roundup Provokes Cell Division Dysfunction at the Level of CDK1/Cyclin B Activation," revealed that Roundup® causes delays in the cell cycles of sea urchins but that the same concentrations of glyphosate alone were ineffective and did not alter cell cycles.²⁶

²³ U.S. Env'tl. Prot. Agency, *Technical Factsheet on: Glyphosate*, *supra*.

²⁴ Caroline Cox, *Glyphosate, Part 2: Human Exposure and Ecological Effects*, 15 J. PESTICIDE REFORM 4 (1995); W.S. Peas et al., *Preventing pesticide-related illness in California agriculture: Strategies and priorities*, *Environmental Health Policy Program Report*, Univ. of Cal. School of Public Health, Calif. Policy Seminar (1993).

²⁵ Martinez, T.T. and K. Brown, *Oral and pulmonary toxicology of the surfactant used in Roundup herbicide*, PROC. WEST. PHARMACOL. SOC. 34:43-46 (1991).

²⁶ Julie Marc, et al., *Pesticide Roundup Provokes Cell Division Dysfunction at the Level of CDK1/Cyclin B Activation*, 15 CHEM. RES. TOXICOL. 326-331 (2002), available at <http://pubs.acs.org/doi/full/10.1021/tx015543g>.

64. A 2004 study by Marc and others, entitled “Glyphosate-based pesticides affect cell cycle regulation,” demonstrated a molecular link between glyphosate-based products and cell cycle dysregulation. The researchers noted that “cell-cycle dysregulation is a hallmark of tumor cells and human cancer. Failure in the cell-cycle checkpoints leads genomic instability and subsequent development of cancers from the initial affected cell.” Further, “[s]ince cell cycle disorders such as cancer result from dysfunction of a unique cell, it was of interest to evaluate the threshold dose of glyphosate affecting the cells.”²⁷

65. In 2005, a study by Francisco Peixoto, entitled “Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation,” demonstrated that Roundup[®]’s effects on rat liver mitochondria are far more toxic than equal concentrations of glyphosate alone. The Peixoto study further suggested that the harmful effects of Roundup[®] on mitochondrial bioenergetics could not be exclusively attributed to glyphosate but could be the result of other chemicals, such as the surfactant POEA, or in the alternative, due to a potential synergic effect between glyphosate and other ingredients in the Roundup[®] formulation.²⁸

66. In 2009, Nora Benachour and Gilles-Eric Seralini published a study examining the effects of Roundup[®] and glyphosate on human umbilical, embryonic, and placental cells. The study tested dilution levels of Roundup[®] and glyphosate that were far below agricultural recommendations, corresponding with low levels of residue in food. The researchers ultimately concluded that supposed “inert” ingredients, and possibly POEA, alter human cell permeability and amplify toxicity of glyphosate alone. The researchers further suggested that assessments of glyphosate toxicity should account for the presence of adjuvants or additional chemicals used in the formulation of the complete pesticide. The study confirmed that the adjuvants present in

²⁷ Julie Marc, et al., *Glyphosate-based pesticides affect cell cycle regulation*, 96 BIOLOGY OF THE CELL 245, 245-249 (2004), available at <http://onlinelibrary.wiley.com/doi/10.1016/j.biolcel.2003.11.010/epdf>.

²⁸ Francisco Peixoto, *Comparative effects of the Roundup and glyphosate on mitochondrial oxidative phosphorylation*, 61 CHEMOSPHERE 1115, 1122 (2005), available at https://www.researchgate.net/publication/7504567_Comparative_effects_of_the_Roundup_and_glyphosate_on_mitochondrial_oxidative_phosphorylation.

Roundup[®] are not, in fact, inert and that Roundup[®] is potentially far more toxic than its active ingredient glyphosate alone.²⁹

67. The results of these studies were at all times available to Defendant. Defendant thus knew or should have known that Roundup[®] is more toxic than glyphosate alone and that safety studies of Roundup[®], Roundup's adjuvants and "inert" ingredients, and/or the surfactant POEA were necessary to protect Plaintiff from Roundup[®].

68. Despite its knowledge that Roundup[®] is considerably more dangerous than glyphosate alone, Defendant continued to promote Roundup[®] as safe.

Recent Worldwide Bans on Roundup[®]/Glyphosate

69. Several countries around the world have instituted bans on the sale of Roundup[®] and other glyphosate-containing herbicides, both before and since IARC first announced its assessment for glyphosate in March 2015, and more countries undoubtedly will follow suit as the dangers of the use of Roundup[®] become more widely known. The Netherlands issued a ban on all glyphosate-based herbicides in April 2014, including Roundup[®], which will take effect by the end of 2015. In issuing the ban, the Dutch Parliament member who introduced the successful legislation stated: "Agricultural pesticides in user-friendly packaging are sold in abundance to private persons. In garden centers, Roundup[®] is promoted as harmless, but unsuspecting customers have no idea what the risks of this product are. Especially children are sensitive to toxic substances and should therefore not be exposed to it."³⁰

70. The Brazilian Public Prosecutor in the Federal District requested that the Brazilian Justice Department suspend the use of glyphosate.³¹

²⁹ Nora Benachour, et al., *Glyphosate Formulations Induce Apoptosis and Necrosis in Human Umbilical, Embryonic, and Placental Cells*, 22 CHEM. RES. TOXICOL. 97-105 (2008), available at <http://big.assets.huffingtonpost.com/france.pdf>.

³⁰ *Holland's Parliament Bans Glyphosate Herbicides*, The Real Agenda, April 14, 2014, available at <http://real-agenda.com/hollands-parliament-bans-glyphosate-herbicides/>.

³¹ Christina Sarich, *Brazil's Public Prosecutor Wants to Ban Monsanto's Chemicals Following Recent Glyphosate-Cancer Link*, GLOBAL RESEARCH, May 14, 2015, available at <http://www.globalresearch.ca/brazils-public->

71. France banned the private sale of Roundup[®] and glyphosate following the IARC assessment for Glyphosate.³²

72. Bermuda banned both the private and commercial sale of glyphosates, including Roundup[®]. The Bermuda government explained its ban as follows: “Following a recent scientific study carried out by a leading cancer agency, the importation of weed spray ‘Roundup’ has been suspended.”³³

73. The Sri Lankan government banned the private and commercial use of glyphosate, particularly out of concern that glyphosate has been linked to fatal kidney disease in agricultural workers.³⁴

74. The government of Colombia announced its ban on using Roundup[®] and glyphosate to destroy illegal plantations of coca, the raw ingredient for cocaine, because of the WHO’s finding that glyphosate is probably carcinogenic.³⁵

Proposition 65 Listing

75. On September 4, 2015, California’s Office of Environmental Health Hazard Assessment (“OEHHA”) published a notice of intent to include glyphosate on the state’s list of known

prosecutor-wants-to-ban-monsantos-chemicals-following- recent-glyphosate-cancer-link/5449440; see Ministério Público Federal, *MPF/DF reforça pedido para que glifosato seja banido do mercado nacional*, April, 14, 2015, available at http://noticias.pgr.mpf.mp.br/noticias/noticias-do-site/copy_of_meio-ambiente-e-patrimonio-cultural/mpf-df-reforca-pedido-para-que-glifosato-seja-banido-do-mercado-nacional.

³² Zoe Schlanger, *France Bans Sales of Monsanto’s Roundup in Garden Centers, 3 Months After U.N. Calls it ‘Probable Carcinogen’*, NEWSWEEK, June 15, 2015, available at <http://www.newsweek.com/france-bans-sale-monsantos-roundup-garden-centers-after-un-names-it-probable-343311>.

³³ *Health Minister: Importation of Roundup Weed Spray Suspended*, Today in Bermuda, May, 11 2015, available at <http://www.todayinbermuda.com/news/health/item/1471-health-minister-importation-of-roundup-weed-spray-suspended>.

³⁴ *Sri Lanka’s New President Puts Immediate Ban on Glyphosate Herbicides*, Sustainable Pulse, May 25, 2015, available at <http://sustainablepulse.com/2015/05/25/sri-lankas-new-president-puts-immediate-ban-on-glyphosate-herbicides/#.VeduYk3bKAw>.

³⁵ *Columbia to ban coca spraying herbicide glyphosate*, BBC, May 10, 2015, available at <http://www.bbc.com/news/world-latin-america-32677411>.

carcinogens under Proposition 65.³⁶ California's Safe Drinking Water and Toxic Enforcement Act of 1986 (informally known as "Proposition 65"), requires the state to maintain and, at least once a year, revise and republish a list of chemicals "known to the State of California to cause cancer or reproductive toxicity."³⁷ The OEHHA determined that glyphosate met the criteria for the listing mechanism under the Labor Code following IARC's assessment of the chemical.³⁸

76. The listing process under the Labor Code is essentially automatic. The list of known carcinogens, at a minimum, must include substances identified by reference in Labor Code § 6382(b)(1). That section of the Labor Code identifies "[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC)." IARC's classification of glyphosate as a Group 2A chemical ("probably carcinogenic to humans") therefore triggered the listing.

77. A business that deploys a listed chemical in its products must provide "clear and reasonable warnings" to the public prior to exposure to the chemical. To be clear and reasonable, a warning must "(1) clearly communicate that the chemical is known to cause cancer, and/or birth defects or other reproductive harm; and (2) effectively reach the person before exposure."³⁹ The law also prohibits the discharge of listed chemicals into drinking water.

³⁶ Cal. Env'tl. Prot. Agency Office of Env'tl. Health Hazard Assessment, Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate (Sept. 4, 2015), http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_LCSet27.pdf.

³⁷ *Frequently Asked Questions*, STATE OF CAL. DEP'T OF JUSTICE, OFFICE OF THE ATTORNEY GENERAL, <http://oag.ca.gov/prop65/faq> (last visited April 19, 2016).

³⁸ Cal. Env'tl. Prot. Agency Office of Env'tl. Health Hazard Assessment, Notice of Intent to List Chemicals by the Labor Code Mechanism: Tetrachlorvinphos, Parathion, Malathion, Glyphosate (Sept. 4, 2015), http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/pdf_zip/090415NOIL_LCSet27.pdf.

³⁹ *Frequently Asked Questions*, STATE OF CAL. DEPARTMENT OF JUSTICE, OFFICE OF THE ATTORNEY GENERAL, *supra*.

78. Monsanto disputed the listing decision and, in January 2016, filed a lawsuit against OEHHA and the agency's acting director, Lauren Zeise, in California state court, seeking declaratory and injunctive relief to prevent OEHHA from listing glyphosate.⁴⁰

79. Monsanto alleged that OEHHA's exclusive reliance on the IARC decision signified that "OEHHA effectively elevated the determination of an ad hoc committee of an unelected, foreign body, which answers to no United States official (let alone any California state official), over the conclusions of its own scientific experts."⁴¹ Monsanto further alleged that the Labor Code listing mechanism presented various constitutional violations because it "effectively empowers an unelected, undemocratic, unaccountable, and foreign body to make laws applicable in California."⁴² Among other things, Monsanto argued that Proposition 65's requirement to provide a "clear and reasonable warning" to consumers that the chemical is a known carcinogen would damage its reputation and violate its First Amendment rights.⁴³

80. The case remains pending.

EFSA Report on Glyphosate

81. On November 12, 2015, the European Food Safety Authority (EFSA), the European Union's primary agency for food safety, reported on its evaluation of the Renewal Assessment Report (RAR) on glyphosate.⁴⁴ The Rapporteur Member State assigned to glyphosate, the German Federal Institute for Risk Assessment (BfR), had produced the RAR as part of the renewal process for glyphosate in the EU.

⁴⁰ Monsanto Company's Verified Petition for Writ of Mandate and Complaint for Preliminary and Permanent Injunctive and Declaratory Relief, *Monsanto Co. v. Office of the Env'tl Health Hazard Assessment, et al.*, No. 16-CECG-00183 (Cal. Super. Ct.) *available at* <http://www.monsanto.com/files/documents/monvoehha.pdf>.

⁴¹ *Id.* at 2.

⁴² *Id.* at 3.

⁴³ *Id.*

⁴⁴ European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, *available at* http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf.

82. BfR sent its draft RAR to EFSA and the RAR underwent a peer review process by EFSA, other member states, and industry groups. As part of the on-going peer review of Germany's reevaluation of glyphosate, EFSA had also received a second mandate from the European Commission to consider IARC's findings regarding the potential carcinogenicity of glyphosate and glyphosate-containing products.

83. Based on a review of the RAR, which included data from industry-submitted unpublished studies, EFSA sent its own report ("Conclusion") to the European Commission, finding that "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008."⁴⁵ EFSA therefore disagreed with IARC: glyphosate was not genotoxic and did not present a carcinogenic threat to humans.

84. In explaining why its results departed from IARC's conclusion, EFSA drew a distinction between the EU and IARC approaches to the study and classification of chemicals.⁴⁶ Although IARC examined "both glyphosate—an active substance—and glyphosate-based formulations, grouping all formulations regardless of their composition," EFSA explained that it considered only glyphosate and that its assessment focuses on "each individual chemical, and each marketed mixture separately."⁴⁷ IARC, on the other hand, "assesses generic agents, including groups of related chemicals, as well as occupational or environmental exposure, and cultural or behavioural practices."⁴⁸ EFSA accorded greater weight to studies conducted with glyphosate alone than studies of formulated products.⁴⁹

85. EFSA went further and noted:

⁴⁵ *Id.*

⁴⁶ EFSA Fact Sheet: Glyphosate, EFSA
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112_en.pdf.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

[A]lthough some studies suggest that certain glyphosate-based formulations may be genotoxic (i.e. damaging to DNA), others that look solely at the active substance glyphosate do not show this effect. It is likely, therefore, that ***the genotoxic effects observed in some glyphosate-based formulations are related to the other constituents or “co-formulants”***. Similarly, certain glyphosate-based formulations display higher toxicity than that of the active ingredient, presumably because of the presence of co-formulants. In its assessment, ***EFSA proposes that the toxicity of each pesticide formulation and in particular its genotoxic potential should be further considered and addressed by Member State authorities while they re-assess uses of glyphosate-based formulations in their own territories.***⁵⁰

86. Notwithstanding its conclusion, EFSA did set exposure levels for glyphosate. Specifically, EFSA proposed an acceptable daily intake (ADI) of 0.5 mg/kg of body weight per day; an acute reference dose (ARfD) of 0.5 mg/kg of body weight; and an acceptable operator exposure level (AOEL) of 0.1 mg/kg bw per day.⁵¹

Leading Scientists Dispute EFSA’s Conclusion

87. On November 27, 2015, 96 independent academic and governmental scientists from around the world submitted an open letter to the EU health commissioner, Vytenis Andriukaitis.⁵² The scientists expressed their strong concerns and urged the commissioner to disregard the “flawed” EFSA report, arguing that “the BfR decision is not credible because it is not supported by the evidence and it was not reached in an open and transparent manner.”⁵³

88. Signatories to the letter included Dr. Christopher J. Portier, Ph.D., and other renowned international experts in the field, some of whom were part of the IARC Working Group assigned to glyphosate.

⁵⁰ *Id.*

⁵¹ European Food Safety Auth., Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, *supra*.

⁵² Letter from Christopher J. Portier et al. to Commission Vytenis Andriukaitis, Open letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR (Nov. 27, 2015), <http://www.zeit.de/wissen/umwelt/2015-11/glyphosat-offener-brief.pdf>; <http://www.theguardian.com/environment/2016/jan/13/eu-scientists-in-row-over-safety-of-glyphosate-weedkiller>.

⁵³ *Id.*

89. In an exhaustive and careful examination, the scientists scrutinized EFSA's conclusions and outlined why the IARC Working Group decision was "by far the more credible":

The IARC WG decision was reached relying on open and transparent procedures by independent scientists who completed thorough conflict-of-interest statements and were not affiliated or financially supported in any way by the chemical manufacturing industry. It is fully referenced and depends entirely on reports published in the open, peer-reviewed biomedical literature. It is part of a long tradition of deeply researched and highly credible reports on the carcinogenicity of hundreds of chemicals issued over the past four decades by IARC and used today by international agencies and regulatory bodies around the world as a basis for risk assessment, regulation and public health policy.⁵⁴

90. With respect to human data, the scientists pointed out that EFSA agreed with IARC that there was "*limited evidence* of carcinogenicity" for non-Hodgkin lymphoma, but EFSA nonetheless dismissed an association between glyphosate exposure and carcinogenicity. IARC applies three levels of evidence in its analyses of human data, including sufficient evidence and limited evidence. EFSA's ultimate conclusion that "there was no unequivocal evidence for a clear and strong association of NHL with glyphosate" was misleading because it was tantamount to IARC's highest level of evidence: "sufficient evidence," which means that a causal relationship has been established. However, the scientists argued, "[l]egitimate public health concerns arise when 'causality is credible,' i.e., when there is *limited evidence*."⁵⁵

91. Among its many other deficiencies, EFSA's conclusions regarding animal carcinogenicity data were "scientifically unacceptable," particularly in BfR's use of historical control data and in its trend analysis. Indeed, BfR's analysis directly contradicted the Organisation for Economic Co-operation and Development ("OECD") testing guidelines while citing and purporting to follow those same guidelines. For instance, the EFSA report dismisses observed trends in tumor incidence "because there are no individual treatment groups that are significantly different from controls and because the maximum observed response is reportedly

⁵⁴ *Id.*

⁵⁵ *Id.*

within the range of the historical control data.” However, according to the scientists, concurrent controls are recommended over historical controls in all guidelines, scientific reports, and publications, and, if it is employed, historical control data “should be from studies in the same timeframe, for the same exact animal strain, preferably from the same laboratory or the same supplier and preferably reviewed by the same pathologist.” BfR’s use of historical control data violated these precautions: “only a single study used the same mouse strain as the historical controls, but was reported more than 10 years after the historical control dataset was developed.” Further deviating from sound scientific practices, the data used by the BfR came from studies in seven different laboratories. The scientists concluded:

BfR reported seven positive mouse studies with three studies showing increases in renal tumors, two with positive findings for hemangiosarcomas, and two with positive findings for malignant lymphomas. BfR additionally reported two positive findings for tumors in rats. Eliminating the inappropriate use of historical data, the unequivocal conclusion is that these are not negative studies, but in fact document the carcinogenicity of glyphosate in laboratory animals.⁵⁶

92. The letter also critiqued the EFSA report’s lack of transparency and the opacity surrounding the data cited in the report: “citations for almost all of the references, even those from the open scientific literature, have been redacted from the document” and “there are no authors or contributors listed for either document, a requirement for publication in virtually all scientific journals.” Because BfR relied on unpublished, confidential industry-provided studies, it is “impossible for any scientist not associated with BfR to review this conclusion with scientific confidence.”⁵⁷

93. On March 3, 2016, the letter was published in the *Journal of Epidemiology & Community Health*.⁵⁸

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ Christopher J. Portier, et al., *Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)*, JOURNAL OF EPIDEMIOLOGY & CMTY. HEALTH, Mar. 3, 2016, available at <http://jech.bmj.com/content/early/2016/03/03/jech-2015-207005.full>.

Statement of Concern Regarding Glyphosate-Based Herbicides

94. On February 17, 2016, a consensus statement published in the journal *Environmental Health*, entitled “Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement,” assessed the safety of glyphosate-based herbicides (GBHs).⁵⁹ The paper’s “focus is on the unanticipated effects arising from the worldwide increase in use of GBHs, coupled with recent discoveries about the toxicity and human health risks stemming from use of GBHs.”⁶⁰ The researchers drew seven factual conclusions about GBHs:

1. GBHs are the most heavily applied herbicide in the world and usage continues to rise;
2. Worldwide, GBHs often contaminate drinking water sources, precipitation, and air, especially in agricultural regions;
3. The half-life of glyphosate in water and soil is longer than previously recognized;
4. Glyphosate and its metabolites are widely present in the global soybean supply;
5. Human exposures to GBHs are rising;
6. Glyphosate is now authoritatively classified as a probable human carcinogen; and
7. Regulatory estimates of tolerable daily intakes for glyphosate in the United States and European Union are based on outdated science.⁶¹

95. The researchers noted that GBH use has increased approximately 100-fold since the 1970s. Further, far from posing a limited hazard to vertebrates, as previously believed, two decades of evidence demonstrated that “several vertebrate pathways are likely targets of action,

⁵⁹ John P. Myers, et al, *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, *Environmental Health* (2016), available at <http://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>.

⁶⁰ *Id.*

⁶¹ *Id.*

including hepatorenal damage, effects on nutrient balance through glyphosate chelating action and endocrine disruption.”⁶²

96. The paper attributes uncertainties in current assessments of glyphosate formulations to the fact that “[t]he full list of chemicals in most commercial GBHs is protected as ‘commercial business information,’ despite the universally accepted relevance of such information to scientists hoping to conduct an accurate risk assessment of these herbicide formulations.” Further, the researchers argue, “[t]he distinction in regulatory review and decision processes between ‘active’ and ‘inert’ ingredients has no toxicological justification, given increasing evidence that several so-called ‘inert’ adjuvants are toxic in their own right.”⁶³

97. Among various implications, the researchers conclude that “existing toxicological data and risk assessments are not sufficient to infer that GBHs, as currently used, are safe.” Further, “GBH-product formulations are more potent, or toxic, than glyphosate alone to a wide array of non-target organisms including mammals, aquatic insects, and fish.” Accordingly, “risk assessments of GBHs that are based on studies quantifying the impacts of glyphosate alone underestimate both toxicity and exposure, and thus risk.” The paper concludes that this “shortcoming has repeatedly led regulators to set inappropriately high exposure thresholds.”⁶⁴

98. The researchers also critique the current practice of regulators who largely rely on “unpublished, non-peer reviewed data generated by the registrants” but ignore “published research because it often uses standards and procedures to assess quality that are different from those codified in regulatory agency data requirements, which largely focus on avoiding fraud.” In the researchers’ view, “[s]cientists independent of the registrants should conduct regulatory tests of GBHs that include glyphosate alone, as well as GBH-product formulations.”⁶⁵

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

99. The researchers also call for greater inclusion of GBHs in government-led toxicology testing programs:

[A] fresh and independent examination of GBH toxicity should be undertaken, and . . . this re-examination be accompanied by systematic efforts by relevant agencies to monitor GBH levels in people and in the food supply, none of which are occurring today. The U.S. National Toxicology Program should prioritize a thorough toxicological assessment of the multiple pathways now identified as potentially vulnerable to GBHs.⁶⁶

100. The researchers suggest that, in order to fill the gap created by an absence of government funds to support research on GBHs, regulators could adopt a system through which manufacturers fund the registration process and the necessary testing:

“[W]e recommend that a system be put in place through which manufacturers of GBHs provide funds to the appropriate regulatory body as part of routine registration actions and fees. Such funds should then be transferred to appropriate government research institutes, or to an agency experienced in the award of competitive grants. In either case, funds would be made available to independent scientists to conduct the appropriate long-term (minimum 2 years) safety studies in recognized animal model systems. A thorough and modern assessment of GBH toxicity will encompass potential endocrine disruption, impacts on the gut microbiome, carcinogenicity, and multigenerational effects looking at reproductive capability and frequency of birth defects.”⁶⁷

FDA Announces Testing of Glyphosate Residue in Foods

101. On February 17, 2016, the U.S. Food and Drug Administration (“FDA”) announced that, for the first time in its history, the agency planned to start testing certain foods for glyphosate residues. FDA spokeswoman Lauren Sucher explained: “The agency is now considering assignments for Fiscal Year 2016 to measure glyphosate in soybeans, corn, milk, and eggs, among other potential foods.”⁶⁸

102. In 2014, the U.S. Government Accountability Office (GAO) had severely rebuked the FDA for its failures to both monitor for pesticide residue, including that of glyphosate, and to

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ Carey Gillam, *FDA to Start Testing for Glyphosate in Food*, TIME, Feb. 17, 2016, available at <http://time.com/4227500/fda-glyphosate-testing/?xid=tcoshare>.

disclose the limitations of its monitoring and testing efforts to the public.⁶⁹ The GAO had cited numerous undisclosed deficiencies in the FDA's process, specifically highlighting its omission of glyphosate testing.

103. Indeed, in the past, both the FDA and the U.S. Department of Agriculture (USDA) had routinely excluded glyphosate from their testing for the residues of hundreds of other pesticides, on the rationale that it was too expensive and unnecessary to protect public health. Ms. Sucher, the FDA spokeswoman, however, now states that "the agency has developed 'streamlined methods' for testing for the weed killer."⁷⁰

104. The FDA's move is significant as the agency possesses enforcement authority and can seek action if pesticide residues exceed enforcement guidelines.⁷¹

European Union Vote on Glyphosate Renewal

105. The license for glyphosate in the European Union (EU) was set to expire on June 30, 2016.

106. Without an extension of the license, Monsanto's Roundup[®] and other glyphosate-based herbicides faced a general phase out in EU markets.⁷²

107. In the months leading up to the license expiration date, protracted meetings and votes among national experts from the 28 EU Member States failed to produce agreement on an extension.

⁶⁹ U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-38, FDA AND USDA SHOULD STRENGTHEN PESTICIDE RESIDUE MONITORING PROGRAMS AND FURTHER DISCLOSE MONITORING LIMITATIONS (2014), available at <http://www.gao.gov/products/GAO-15-38>.

⁷⁰ Gillam, *supra* note 68.

⁷¹ *Id.*; Pesticide Q&A, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm114958.htm> (last visited April 19, 2016).

⁷² Philip Blenkinsop, Alissa de Carbonnel & Barbara Lewis European, *Commission to extend glyphosate license for 18 months*, REUTERS, June 28, 2016, available at <http://www.reuters.com/article/us-health-eu-glyphosate-idUSKCN0ZE25B>.

108. For instance, on March 4, 2016, *The Guardian* reported that France, the Netherlands, and Sweden did not support EFSA's assessment that glyphosate was harmless.⁷³ The paper quoted the Swedish environment minister, Åsa Romson, as stating: "We won't take risks with glyphosate and we don't think that the analysis done so far is good enough. We will propose that no decision is taken until further analysis has been done and the Efsa scientists have been more transparent about their considerations."⁷⁴

109. The Netherlands argued that relicensing should be placed on hold until after a separate evaluation of glyphosate's toxicity can be conducted.⁷⁵ Leading up to the vote, Italy joined the other EU states in opposing the license renewal, citing health concerns.⁷⁶

110. On June 6, 2016, Member States voted but failed to reach a qualified majority in favor or against the re-authorization of glyphosate.⁷⁷

111. On June 29, 2016, the EU Commission extended the European license for glyphosate for 18 months to allow the European Chemical Agency to rule on the safety of the chemical, which is expected by the end of 2017.⁷⁸

112. On July 11, 2016, the EU voted in favor of a proposal to restrict the conditions of use of glyphosate in the EU, including a ban on common co-formulant POE-tallowamine (POEA) from all glyphosate-based herbicides, including Roundup.⁷⁹

⁷³ Arthur Neslen, *EU states rebel against plans to relicense weedkiller glyphosate*, THE GUARDIAN, Mar. 4, 2016, available at <http://www.theguardian.com/environment/2016/mar/04/eu-states-rebel-against-plans-to-relicense-weedkiller-glyphosate>.

⁷⁴ *Id.*

⁷⁵ Arthur Neslen, *Vote on Controversial weedkiller's European licence postponed*, THE GUARDIAN, Mar. 8, 2016, available at <http://www.theguardian.com/environment/2016/mar/08/eu-vote-on-controversial-weedkiller-licence-postponed-glyphosate>.

⁷⁶ *Id.*

⁷⁷ Manon Flausch, *Commission prolongs glyphosate license by 18 months*, EURACTIV, June 29, 2016, available at <http://www.euractiv.com/section/agriculture-food/news/commission-prolongs-glyphosate-licence-by-18-months/>

⁷⁸ Arthur Neslen, *Controversial chemical in Roundup weedkiller escapes immediate ban*, THE GUARDIAN, June 29, 2016, available at <https://www.theguardian.com/business/2016/jun/29/controversial-chemical-roundup-weedkiller-escapes-immediate-ban>

113. These restrictions, which are non-binding on the EU states, are expected to apply until the European Chemicals Agency issues an opinion on the chemical's safety.⁸⁰

Plaintiff William Setzer's Exposure to Roundup®

114. William Setzer has used Roundup for around 15 years on his property as well as on his in-laws' property.

115. Mr. Setzer frequently buys Roundup in its concentrated liquid form and has to personally mix it to obtain the correct application ratio

116. In August 2016, doctors diagnosed Mr. Setzer with Non-Hodgkin lymphoma.

117. Since his diagnosis, Mr. Setzer has been treated for the cancer.

118. During the entire time in which Mr. Setzer was exposed to Roundup®, he did not know that exposure to Roundup® was injurious to his health or the health of others.

119. Mr. Setzer first learned that exposure to Roundup® can cause NHL and other serious illnesses sometime after July 29, 2015, when IARC first published its evaluation of glyphosate.

Tolling of the Statute of Limitations

Discovery Rule Tolling

120. Plaintiffs had no way of knowing about the risk of serious illness associated with the use of and/or exposure to Roundup® and glyphosate until IARC released its formal assessment of glyphosate in July 2015. This is the quintessential case for tolling.

⁷⁹ Sarantis Michalopoulos, *EU agrees ban on glyphosate co-formulant*, EURACTIV, July 11, 2016, available at http://www.euractiv.com/section/agriculture-food/news/eu-agrees-ban-on-glyphosate-co-formulant/?nl_ref=16562829

⁸⁰ See Arthur Neslen, *Controversial chemical in Roundup weedkiller escapes immediate ban*, THE GUARDIAN, June 29, 2016.

121. Within the time period of any applicable statutes of limitations, Plaintiffs could not have discovered, through the exercise of reasonable diligence, that exposure to Roundup[®] and glyphosate is injurious to human health.

122. Plaintiffs did not discover, and did not know of facts that would cause a reasonable person to suspect, the risks associated with the use of and/or exposure to Roundup[®] and glyphosate; nor would a reasonable and diligent investigation by him have disclosed that Roundup[®] and glyphosate would cause his illness.

123. For these reasons, all applicable statutes of limitations have been tolled by operation of the discovery rule with respect to Plaintiffs' claims.

Fraudulent Concealment Tolling

124. All applicable statutes of limitations have also been tolled by Monsanto's knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action.

125. Instead of disclosing critical safety information about Roundup[®] and glyphosate, Monsanto has consistently and falsely represented the safety of its Roundup[®] products.

Estoppel

126. Monsanto was under a continuous duty to disclose to consumers, users and other persons coming into contact with its products, including Plaintiff, accurate safety information concerning its products and the risks associated with the use of and/or exposure to Roundup[®] and glyphosate.

127. Instead, Monsanto knowingly, affirmatively, and actively concealed safety information concerning Roundup[®] and glyphosate and the serious risks associated with the use of and/or exposure to its products.

128. Based on the foregoing, Monsanto is estopped from relying on any statutes of limitations in defense of this action.

Claims for Relief

Count One **Strict Liability (Design Defect)**

129. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

130. Plaintiffs bring this strict liability claim against Defendant for defective design.

131. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup[®] products, which are defective and unreasonably dangerous to consumers, users, and other persons coming into contact with them, including Mr. Setzer, thereby placing Roundup[®] products into the stream of commerce. These actions were under the ultimate control and supervision of Defendant.

132. At all times relevant to this litigation, Defendant designed, researched, developed, formulated, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the Roundup[®] products used by Mr. Setzer, and/or to which Mr. Setzer were exposed, as described above.

133. At all times relevant to this litigation, Defendant's Roundup[®] products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public, and, in particular, Mr. Setzer.

134. At all times relevant to this litigation, Defendant's Roundup[®] products reached the intended consumers, handlers, and users or other persons coming into contact with these products in Illinois and throughout the United States, including Mr. Setzer, without substantial

change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

135. Defendant's Roundup[®] products, as researched, tested, developed, designed, licensed, formulated, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant, were defective in design and formulation in that when they left the hands of the Defendant's manufacturers and/or suppliers, they were unreasonably dangerous because they were not as safe as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

136. Defendant's Roundup[®] products, as researched, tested, developed, designed, licensed, formulated, manufactured, packaged, labeled, distributed, sold, and marketed by Defendant, were defective in design and formulation in that when they left the hands of Defendant's manufacturers and/or suppliers, the foreseeable risks associated with these products' reasonably foreseeable uses exceeded the alleged benefits associated with their design and formulation.

137. Therefore, at all times relevant to this litigation, Defendant's Roundup[®] products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendant, were defective in design and formulation, in one or more of the following ways:

- a) When placed in the stream of commerce, Defendant's Roundup[®] products were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would expect.
- b) When placed in the stream of commerce, Defendant's Roundup[®] products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer and other serious illnesses when used in a reasonably anticipated manner.
- c) When placed in the stream of commerce, Defendant's Roundup[®] products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner.

- d) Defendant did not sufficiently test, investigate, or study its Roundup[®] products and, specifically, the active ingredient glyphosate.
- e) Exposure to Roundup[®] and glyphosate-containing products presents a risk of harmful side effects that outweighs any potential utility stemming from the use of the herbicide.
- f) Defendant knew or should have known at the time of marketing its Roundup[®] products that exposure to Roundup[®] and specifically, its active ingredient glyphosate, could result in cancer and other severe illnesses and injuries.
- g) Defendant did not conduct adequate post-marketing surveillance of its Roundup[®] products.
- h) Defendant could have employed safer alternative designs and formulations.

138. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendant's Roundup[®] products in an intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

139. Plaintiffs could not have reasonably discovered the defects and risks associated with Roundup[®] or glyphosate-containing products before or at the time of exposure.

140. The harm caused by Defendant's Roundup[®] products far outweighed their benefit, rendering Defendant's products dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendant's Roundup[®] products were and are more dangerous than alternative products and Defendant could have designed its Roundup[®] products to make them less dangerous. Indeed, at the time that Defendant designed its Roundup[®] products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

141. At the time Roundup[®] products left Defendant's control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without

substantially impairing the reasonably anticipated or intended function of Defendant's Roundup[®] herbicides.

142. Defendant's defective design of Roundup[®] amounts to willful, wanton, and/or reckless conduct by Defendant.

143. Therefore, as a result of the unreasonably dangerous condition of its Roundup[®] products, Defendant is strictly liable to Plaintiff.

144. The defects in Defendant's Roundup[®] products were substantial and contributing factors in causing Plaintiff's grave injuries, and, but for Defendant's misconduct and omissions, Plaintiff would not have sustained his injuries.

145. As a direct and proximate result of Defendant placing its defective Roundup[®] products into the stream of commerce, Plaintiff has suffered and continues to suffer grave injuries, and he has endured pain and discomfort, as well as economic hardship, including considerable financial expenses for medical care and treatment. Plaintiff will continue to incur these expenses in the future.

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiffs also demand a jury trial on the issues contained herein.

Count Two
Strict Liability (Failure to Warn)

146. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

147. Plaintiff brings this strict liability claim against Defendant for failure to warn.

148. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Roundup[®]

products, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Roundup[®] and specifically, the active ingredient glyphosate. These actions were under the ultimate control and supervision of Defendant.

149. Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Roundup[®] products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, Plaintiff's employers, Plaintiff's co-workers, and persons responsible for consumers (such as employers), and Defendant therefore had a duty to warn of the risks associated with the reasonably foreseeable uses (and misuses) of Roundup[®] and glyphosate-containing products and a duty to instruct on the proper, safe use of these products.

150. At all times relevant to this litigation, Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and take such steps as necessary to ensure that its Roundup[®] products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn Plaintiff of the dangers associated with Roundup[®] use and exposure, and a continuing duty to instruct on the proper, safe use of these products. Defendant, as manufacturer, seller, or distributor of chemical herbicides, is held to the knowledge of an expert in the field.

151. At the time of manufacture, Defendant could have provided warnings or instructions regarding the full and complete risks of Roundup[®] and glyphosate-containing products because it knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to these products.

152. At all times relevant to this litigation, Defendant failed to investigate, study, test, or promote the safety of its Roundup[®] products. Defendant also failed to minimize the dangers to

users and consumers of its Roundup[®] products and to those who would foreseeably use or be harmed by Defendant's herbicides, including Plaintiff.

153. Despite the fact that Defendant knew or should have known that Roundup[®] products posed a grave risk of harm, it failed to warn of the dangerous risks associated with their use and exposure. The dangerous propensities of its products and the carcinogenic characteristics of glyphosate, as described above, were known to Defendant, or scientifically knowable to Defendant through appropriate research and testing by known methods, at the time it distributed, supplied, or sold the product, and not known to end users and consumers, such as Plaintiff and Plaintiff's employers.

154. Defendant knew or should have known that its Roundup[®] and glyphosate-containing products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendant failed to adequately warn consumers and reasonably foreseeable users of the risks of exposure to these products. Defendant has wrongfully concealed information concerning the dangerous nature of Roundup[®] and its active ingredient glyphosate, and further made false and/or misleading statements concerning the safety of Roundup[®] and glyphosate.

155. At all times relevant to this litigation, Defendant's Roundup[®] products reached the intended consumers, handlers, and users or other persons coming into contact with these products throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendant.

156. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendant's Roundup[®] products in their intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

157. Plaintiff could not have reasonably discovered the defects and risks associated with Roundup[®] or glyphosate-containing products before or at the time of Plaintiff's exposure. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendant.

158. Defendant knew or should have known that the minimal warnings disseminated with its Roundup[®] products were inadequate, but it failed to communicate adequate information on the dangers and safe use/exposure and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended, and reasonably foreseeable uses, including agricultural and horticultural applications.

159. The information that Defendant did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled agricultural workers, horticultural workers and/or at-home users such as Plaintiff to utilize the products safely and with adequate protection. Instead, Defendant disseminated information that was inaccurate, false, and misleading and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries associated with use of and/or exposure to Roundup[®] and glyphosate; continued to aggressively promote the efficacy of its products, even after it knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of exposure to Roundup[®] and glyphosate.

160. To this day, Defendant has failed to adequately and accurately warn of the true risks of Plaintiff's injuries associated with the use of and exposure to Roundup[®] and its active ingredient glyphosate, a probable carcinogen.

161. As a result of their inadequate warnings, Defendant's Roundup[®] products were defective and unreasonably dangerous when they left the possession and/or control of Defendant, were distributed by Defendant, and used by Plaintiff.

162. Defendant is liable to Plaintiff for injuries caused by its failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of its Roundup[®] products and the risks associated with the use of or exposure to Roundup[®] and glyphosate.

163. The defects in Defendant's Roundup[®] products were substantial and contributing factors in causing Plaintiff's injuries, and, but for Defendant's misconduct and omissions, Plaintiff would not have sustained his injuries.

164. Had Defendant provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Roundup[®] products, Plaintiff could have avoided the risk of developing injuries as alleged herein and Plaintiff and Plaintiff's employers could have obtained alternative herbicides.

165. As a direct and proximate result of Defendant placing its defective Roundup[®] products into the stream of commerce, Plaintiff has suffered and continues to suffer severe injuries, and had endured physical pain and discomfort, as well as economic hardship, including considerable financial expenses for medical care and treatment. Plaintiff will continue to incur these expenses in the future.

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands a jury trial on the issues contained herein.

Count Three **Negligence**

166. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

167. Defendant, directly or indirectly, caused Roundup[®] products to be sold, distributed, packaged, labeled, marketed, and/or promoted.

168. Defendant, directly or indirectly, caused Roundup[®] products to be purchased and/or used by Plaintiff.

169. At all times relevant to this litigation, Defendant had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of its Roundup[®] products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers, users, and other persons coming into contact with the product.

170. At all times relevant to this litigation, Defendant had a duty to exercise reasonable care in the marketing, advertisement, and sale of its Roundup[®] products. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Roundup[®] and appropriate, complete, and accurate warnings concerning the potential adverse effects of exposure to Roundup[®] and, in particular, its active ingredient glyphosate.

171. At all times relevant to this litigation, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Roundup[®] and specifically, the carcinogenic properties of the chemical glyphosate.

172. Accordingly, at all times relevant to this litigation, Defendant knew or, in the exercise of reasonable care, should have known that use of or exposure to its Roundup[®] products could cause Plaintiff's injuries and thus created a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

173. Defendant knew or, in the exercise of reasonable care, should have known that Roundup[®] is more toxic than glyphosate alone and that safety studies on Roundup[®], Roundup[®]'s adjuvants and "inert" ingredients, and/or the surfactant POEA were necessary to protect Plaintiff from Roundup[®].

174. Defendant knew or, in the exercise of reasonable care, should have known that tests limited to Roundup's active ingredient glyphosate were insufficient to prove the safety of Roundup[®].

175. Defendant also knew or, in the exercise of reasonable care, should have known that users and consumers of Roundup[®] were unaware of the risks and the magnitude of the risks associated with the use of and/or exposure to Roundup[®] and glyphosate-containing products.

176. As such, Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of its Roundup[®] products, in that Defendant manufactured and produced defective herbicides containing the chemical glyphosate, knew or had reason to know of the defects inherent in its products, knew or had reason to know that a user's or consumer's exposure to the products created a significant risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of these risks and injuries.

177. Defendant failed to appropriately and adequately test Roundup[®], Roundup[®]'s adjuvants and "inert" ingredients, and/or the surfactant POEA to protect Plaintiff from Roundup[®].

178. Despite its ability and means to investigate, study, and test its products and to provide adequate warnings, Defendant has failed to do so. Indeed, Defendant has wrongfully concealed information and has further made false and/or misleading statements concerning the safety and/or exposure to Roundup[®] and glyphosate.

179. Defendant's negligence included:

- a) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing its Roundup[®] products without thorough and adequate pre- and post-market testing;
- b) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing Roundup[®] while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of exposure to glyphosate, and, consequently, the risk of serious harm associated with human use of and exposure to Roundup[®];

- c) Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Roundup[®] products and glyphosate-containing products were safe for their intended use in agriculture, horticulture, and at-home use;
- d) Failing to undertake sufficient studies and conduct necessary tests to determine the safety of “inert” ingredients and/or adjuvants contained within Roundup[®], and the propensity of these ingredients to render Roundup[®] toxic, increase the toxicity of Roundup[®], whether these ingredients are carcinogenic, magnify the carcinogenic properties of Roundup[®], and whether or not “inert” ingredients and/or adjuvants were safe for use;
- e) Failing to use reasonable and prudent care in the design, research, manufacture, formulation, and development of Roundup[®] products so as to avoid the risk of serious harm associated with the prevalent use of Roundup[®]/glyphosate as an herbicide;
- f) Failing to design and manufacture Roundup[®] products so as to ensure they were at least as safe and effective as other herbicides on the market;
- g) Failing to provide adequate instructions, guidelines, and safety precautions to those persons who Defendant could reasonably foresee would use and/or be exposed to its Roundup[®] products;
- h) Failing to disclose to Plaintiff, users, consumers, and the general public that the use of and exposure to Roundup[®] presented severe risks of cancer and other grave illnesses;
- i) Failing to warn Plaintiff, users, consumers, and the general public that the product’s risk of harm was unreasonable and that there were safer and effective alternative herbicides available to Plaintiff and other users or consumers;

- j) Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Roundup[®] and glyphosate-containing products;
- k) Representing that its Roundup[®] products were safe for their intended use when, in fact, Defendant knew or should have known that the products were not safe for their intended use;
- l) Declining to make or propose any changes to Roundup[®] products' labeling or other promotional materials that would alert the consumers and the general public of the risks of Roundup[®] and glyphosate;
- m) Advertising, marketing, and recommending the use of Roundup[®] products, while concealing and failing to disclose or warn of the dangers known by Defendant to be associated with or caused by the use of or exposure to Roundup[®] and glyphosate;
- n) Continuing to disseminate information to its consumers, which indicate or imply that Defendant's Roundup[®] products are not unsafe for use in the agricultural, horticultural industries, and/or home use; and
- o) Continuing the manufacture and sale of its products with the knowledge that the products were unreasonably unsafe and dangerous.

180. Defendant knew and/or should have known that it was foreseeable that consumers and/or users, such as Plaintiff, would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Roundup[®].

181. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Roundup[®] or its active ingredient glyphosate.

182. Defendant's negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

183. Defendant's conduct, as described above, was reckless. Defendant regularly risks the lives of consumers and users of its products, including Plaintiff, with full knowledge of the dangers of its products. Defendant has made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff. Defendant's reckless conduct therefore warrants an award of punitive damages.

184. As a proximate result of Defendant's wrongful acts and omissions in placing its defective Roundup[®] products into the stream of commerce without adequate warnings of the hazardous and carcinogenic nature of glyphosate, Plaintiff has suffered and continues to suffer severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, has suffered economic losses (including significant expenses for medical care and treatment) and will continue to incur these expenses in the future.

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiffs also demand a jury trial on the issues contained herein.

Count Four
Breach of Express Warranty

185. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

186. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting its Roundup[®] products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Roundup[®] products into the stream of commerce. These actions were under the ultimate control and supervision of Defendant.

187. At all times relevant to this litigation, Defendant expressly represented and warranted to the purchasers of its Roundup[®] products, by and through statements made by Defendant in labels, publications, package inserts, and other written materials intended for consumers and the general public, that its Roundup[®] products were safe to human health and the environment, effective, fit, and proper for their intended use. Defendant advertised, labeled, marketed, and promoted Roundup[®] products, representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that its Roundup[®] products would conform to the representations.

188. These express representations include incomplete warnings and instructions that purport, but fail, to include the complete array of risks associated with use of and/or exposure to Roundup[®] and glyphosate. Defendant knew and/or should have known that the risks expressly included in Roundup[®] warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendant expressly represented that its Roundup[®] products were safe and effective, that they were safe and effective for use by individuals such as Plaintiff, and/or that they were safe and effective as agricultural herbicides.

189. The representations about Roundup[®], as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

190. Defendant placed its Roundup[®] products into the stream of commerce for sale and recommended their use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of and exposure to Roundup[®] and its active ingredient glyphosate.

191. Defendant breached these warranties because, among other things, its Roundup[®] products were defective, dangerous, unfit for use, did not contain labels representing the true and

adequate nature of the risks associated with their use, and were not merchantable or safe for their intended, ordinary, and foreseeable use and purpose. Specifically, Defendant breached the warranties in the following ways:

- a) Defendant represented through its labeling, advertising, and marketing materials that its Roundup[®] products were safe, and fraudulently withheld and concealed information about the risks of serious injury associated with use of and/or exposure to Roundup[®] and glyphosate by expressly limiting the risks associated with use and/or exposure within its warnings and labels; and
- b) Defendant represented that its Roundup[®] products were safe for use and fraudulently concealed information that demonstrated that glyphosate, the active ingredient in Roundup[®], had carcinogenic properties, and that its Roundup[®] products, therefore, were not safer than alternatives available on the market.

192. Monsanto's warranties and representations, as described herein, concerning the qualities of Roundup[®] products, became a basis of the bargain for Plaintiff's employers' purchases of Roundup[®] products. Therefore, vertical privity is not required.

193. On information and belief, Plaintiff's employers justifiably and detrimentally relied on the express warranties and representations of Defendant in the purchase and use of its Roundup[®] products. When Plaintiff's employers made the decision to purchase Roundup[®], they reasonably relied upon Defendant to disclose known defects, risks, dangers, and side effects of Roundup[®] and glyphosate.

194. Plaintiff was exposed to the labels on the Roundup[®] products that he mixed and applied as part of his job.

195. Defendant had sole access to material facts concerning the nature of the risks associated with its Roundup[®] products as expressly stated within its warnings and labels, and Defendant knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly included in Roundup[®] warnings and labels were inadequate and inaccurate.

196. Plaintiff had no knowledge of the falsity or incompleteness of Defendant's statements and representations concerning Roundup[®].

197. Plaintiff used and/or was exposed to the use of Roundup[®] as researched, developed, designed, tested, formulated, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendant.

198. Had the warnings and labels for Roundup[®] products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the products were safe for their intended use, Plaintiff could have avoided the injuries complained of herein.

199. As a direct and proximate result of Defendant's wrongful acts and omissions, Plaintiff has suffered severe injuries. Plaintiff has endured pain and suffering, has suffered economic losses (including significant expenses for medical care and treatment), and will continue to incur these expenses in the future.

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiffs also demand a jury trial on the issues contained herein.

Count Five
Breach of Implied Warranty of Merchantability

200. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein, and further allege:

201. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, formulating, manufacturing, marketing, selling, distributing, and promoting its Roundup[®] products, which are defective and unreasonably dangerous to users and consumers, including Plaintiff, thereby placing Roundup[®] products into the stream of commerce.

202. These actions were under the ultimate control and supervision of Defendant.

203. Before the time that Plaintiff was exposed to the use of the aforementioned Roundup[®] products, Defendant impliedly warranted to its consumers and users—including Plaintiff and Plaintiff's employers—that its Roundup[®] products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as horticultural herbicides.

204. Defendant, however, failed to disclose that Roundup[®] has dangerous propensities when used as intended and that the use of and/or exposure to Roundup[®] and glyphosate- containing products carries an increased risk of developing severe injuries, including Plaintiff's injuries.

205. Upon information and belief, Plaintiff and Plaintiff's employers reasonably relied upon the skill, superior knowledge and judgment of Defendant and upon its implied warranties that the Roundup[®] products were of merchantable quality and fit for their intended purpose or use.

206. Upon information and belief, Plaintiff and Plaintiff's employers reasonably relied upon the skill, superior knowledge and judgment of Defendant and upon its implied warranties that the Roundup[®] products were of merchantable quality and fit for their intended purpose or use.

207. The Roundup[®] products were expected to reach and did in fact reach consumers and users, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendant.

208. At all times relevant to this litigation, Defendant was aware that consumers and users of its products, including Plaintiff, would use Roundup[®] products as marketed by Defendant, which is to say that Plaintiff was the foreseeable user of Roundup[®].

209. Defendant intended that its Roundup[®] products be used in the manner in which Plaintiff in fact used them and Defendant impliedly warranted each product to be of merchantable quality, safe, and fit for this use, despite the fact that Roundup[®] was not adequately tested or researched.

210. In reliance upon Defendant's implied warranty, Plaintiff used Roundup[®] as instructed and labeled and in the foreseeable manner intended, recommended, promoted and marketed by Defendant.

211. Neither Plaintiff nor Plaintiff's employers could have reasonably discovered or known of the risks of serious injury associated with Roundup[®] or glyphosate.

212. Defendant breached its implied warranty to Plaintiff in that its Roundup[®] products were not of merchantable quality, safe, or fit for their intended use, or adequately tested. Roundup[®] has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

213. The harm caused by Defendant's Roundup[®] products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

214. As a direct and proximate result of Defendant's wrongful acts and omissions Plaintiff has suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, has suffered economic loss (including significant expenses for medical care and treatment) and will continue to incur these expenses in the future.

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiffs also demand a jury trial on the issues contained herein.

Prayer for Relief

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor and against Monsanto, awarding as follows:

- A. compensatory damages in an amount to be proven at trial;
- B. punitive damages;

C. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

D. any other relief the Court may deem just and proper.

March 20, 2017.

Respectfully Submitted,

/s/ James G. O'Brien

James G. O'Brien (0088460)

ZOLL & KRANZ, LLC

6620 W. Central Ave., Suite 100

Toledo, OH 43617

Tel. (419) 841-9623

Fax (419) 841-9719

Email jim@toledolaw.com

Counsel for Plaintiffs William Setzer and Pamela Setzer

Jury Demand

Plaintiffs hereby request a trial by jury on all triable issues.

/s/ James G. O'Brien

James G. O'Brien (0088460)

Counsel for Plaintiffs William Setzer and Pamela Setzer